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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,195	ZANCOPE-OLIVEIRA ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *10-15,21-30 and 34-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 16-20, 31-33, and 45-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed November 19, 2003 has been received and entered. New claims 45-49 have been added. Consequently claims 1-49 are pending in the instant application, of which claims 10-15, 21-30, and 34-44 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1, 4-9, 16, 18-20, 31, and 33 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained. Additionally this rejection is applied to newly added claims 45-49.

Applicants are asserting that the Examiner is attempting to interpret the meaning of the words in the claims that have been ascribed specific meaning in the specification, without the use of said specification. The specification can be used in interpreting claim language when the specification provides definitions for terms appearing in the claims. *In re Vogel*, 422 F.2d 438, 441 164 USPQ 619, 612 (CCPA 1970). Specifically, Applicants point to the term fragment as being defined on page 16, lines 13-23, and using this definition the Examiner cannot properly construe the claims to "include fragments as small as a single nucleotide." Applicants further

assert that the phrase "substantially the same" is also given meaning in the specification on page 19, line 24 through page 20, line 15. Applicants finally assert that the preamble of the claim requires that the nucleic acid is specific to Histoplasma capsulatum.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants are asserting that the Examiner is attempting to interpret the meaning of the words in the claims that have been ascribed specific meaning in the specification, without the use of said specification, specifically, the term fragment as being defined on page 16, lines 13-23, and using this definition the Examiner cannot properly construe the claims to "include fragments as small as a single nucleotide." However, Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, to the extent that Applicants assert that the specification provides a "definition" Applicants are respectfully directed to their own specification. Page 16 sets forth that the term "fragment as used herein in relation to a nucleic acid means a subsequence of the nucleic acid which is of sufficient size and confirmation to properly function as a hybridization probe... or in ***another manner*** characteristic of nucleic acids." (Emphasis added). Given that single nucleotides are the building blocks of nucleic acids they are deemed to be of a sufficient size and confirmation to act in a manner characteristic of nucleic acids. Accordingly, a single nucleotide is within Applicants own definition of the term "fragment."

Second, Applicants further assert that the phrase "substantially the same" is also given meaning in the specification on page 19, line 24 through page 20, line 15. However, Applicants are again directed to their own definition. Page 19 sets forth that "substantially the same as in relation to the nucleotide sequence set forth in the Sequence Listing as SEQ ID NO: 1 refers to a nucleic acid having a nucleotide sequence which is ***similar*** to the nucleotide sequence set forth in the Sequence Listing as SEQ ID NO: 1... and which retains the ***functions*** of such nucleic acid." (Emphasis added). What definition is offered by the word similar? Furthermore, what function is being retained, given that every nucleic acid is capable of encoding an amino acid protein sequence, the function of encoding a protein would be a retained function of every DNA sequence. Consequently, Applicants "definition" does not allow those of skill in the art to recognize members of the genus.

Finally Applicants assert that the preamble of the claim requires that the nucleic acid is specific to Histoplasma capsulatum. However, Applicants are again directed back to the claim language. The claims are directed to "fragments" and "substantially the same as" sequences which are specific to Histoplasma capsulatum M antigen. These members of the genus have not been adequately described as explained above.

Claims 1, 4-9, 16, 18-20, 31, 33 and 45-49 recite isolated nucleic acids, vectors and host cells which are specific to Histoplasma capsulatum M antigen comprising SEQ ID NO: 1, or nucleic acids "substantially the same as SEQ ID NO: 1" and "fragments of SEQ ID NO: 1."

The written description of the specification is fully enabled for the full length SEQ ID NO: 1, however, the written description requirement is not met for "substantially the same as SEQ ID NO: 1 or fragments of SEQ ID NO: 1."

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 1 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by SEQ ID NO: 1 which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Furthermore, Applicants recitation of "fragments of SEQ ID NO: 1" can be construed to include fragments as small as a single nucleotide. This combined with the recitation of "having" which is deemed to be equivalent to "comprising" encompasses every single DNA molecule

isolated since the beginning of time. Traditional phrases such as "having" must be interpreted in light of the specification to determine whether open or closed claim language is intended. (See MPEP 2111.03). Transitional phrases such as "having" must be interpreted in light of the specification to determine whether open or closed claim language is intended. (See *Lampi Corp. v. American Power Products Inc.*, 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) (The term "having" was interpreted as open terminology, allowing the inclusion of other components in addition to those recited). In view that Applicant's specification does not set forth of a definition for the term "having" the recitation of "having" is deemed to encompass open language.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 1, 4-5, 8-9, 16, 18, 20, 31 and 33 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "substantially the same." is maintained.

Applicants are asserting that the term "substantially the same" has a very specific meaning given in the specification, and that the definition in the specification states that the sequences will have less than about 10% divergence.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Page 19 sets forth that "substantially the same as in relation to the nucleotide sequence set forth in the Sequence Listing as SEQ ID NO: 1 refers to a nucleic acid having a nucleotide sequence which is ***similar*** to the nucleotide sequence set forth in the Sequence Listing as SEQ ID NO: 1... and which retains the ***functions*** of such nucleic acid." (Emphasis added). What definition is offered by the word similar? One of skill in the art would still be perplexed as to the metes and bounds of the claimed invention. Furthermore, Applicants assert that the specification defines the term to "have less than about 10% divergence." Applicants are again respectfully directed back to the specification. The correct quote on page 20 is "***Generally***, these nucleic acids will have a nucleotide sequence which has less than about 10% divergence..." (Emphasis added). "Generally" is simply not a definition.

For reasons of record as well as the arguments set forth above this rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. The rejection of claims 1-9, 16-20 and 31-33 under 35 U.S.C. 102(a) as being anticipated by Zancope-Oliveria *et al* is maintained. Additionally this rejection is applied to newly added claims 45-49.

Applicants are asserting that the cited publication represents the Applicants' own work as every author listed is also an inventor. Applicants further assert that the cited art could not be 102(a) prior art as the invention had to be invented before the publication date of the citation. Applicants finally conclude that the requirements for inclusion as an inventor are different from those of authorship, and that it is not necessary for Applicants to explain why an inventor was excluded from authorship for a publication.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the cited publication represents Applicants' own work. However, Applicants will note that there are multiple author names on the publication which do not appear on the patent application. Consequently, this is under the statute a work "by another."

Second, Applicants further assert that the cited art could not be 102(a) prior art as the invention had to be invented before the publication date of the citation. However, to the extent that the Examiner understands this statement, it has no bearing on the statute. If the publication was made publicly available prior to the filing date of the instant application, and it is a work "by another" it qualifies as a 102 reference, period.

Finally, Applicants conclude that the requirements for inclusion as an inventor are different from those of authorship, and that it is not necessary for Applicants to explain why an inventor was excluded from authorship for a publication. The Examiner is not asking for an explanation. However, the rejection is proper under the 102 statutes. The publication consists of a reference produced by another prior to the filing date of the instant application.

The claims are directed to an isolated nucleic acid specific to Histoplasma capsulatum M antigen comprising, a nucleic acid comprising SEQ ID NO: 1 (which encodes the M antigen), complementary to SEQ ID NO: 1, substantially the same as SEQ ID NO: 1, and fragments of SEQ ID NO: 1, as well as vectors and host cells comprising the DNA sequences.

Zancope-Oliveria *et al* (IDS reference A13) disclose of the isolation and characterization of the M antigen of Histoplasma capsulatum. (See abstract).

In view that Zancope-Oliveria *et al* disclose of the isolation of the DNA encoding the M antigen of Histoplasma capsulatum, as well as its presence with a vector and host cell, the disclosure of Zancope-Oliveria *et al* is deemed to anticipate the claimed invention.

For reasons of record, as well as the arguments set forth above, this rejection is maintained.

4. The rejection of claims 1 and 4-9 under 35 U.S.C. 102(b) as being anticipated by Stryer is maintained. Additionally this rejection is applied to newly added claims 45-49.

Applicants are asserting that as pointed out above, the term "fragment" read in light of the specification cannot be interpreted as a single nucleotide. Applicants further assert that as amended the preamble states that the nucleic acid of the claim must be specific to "H. capsulatum M antigen."

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, the term fragment does encompass single nucleotides as explained above in paragraph number 1 above.

Second, Applicants assert that as amended the preamble states that the nucleic acid of the claim must be specific to H. capsulatum. However, this limitation has been structurally met. The nucleotide disclosed by Stryer is a 100% match to a "fragment" of SEQ ID NO: 1. Accordingly, in light of this exact match, the structure disclosed by Stryer is deemed to be specific for

Histoplasma capsulatum M antigen. Furthermore, although the reference appears to disclose the same nucleic acid fragment as claimed by applicants, the reference does not disclose the fragment as being isolated from Histoplasma capsulatum M antigen. However the purification or production of a product by a particular process or from a particular source does not impart novelty to a product when the product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner.

See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

Therefore even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art.

See In re King, 107 F. 2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F. 2d 599, 601, 38 USPQ 143-145 (CCPA 1938); In re Bergy, 563 F. 2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) vacated 438 US 902 (1978); and United States v. Ciba-Geigy Corp, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

The claims are directed to an isolated nucleic acid specific to Histoplasma capsulatum comprising a nucleotide sequence as set forth in SEQ ID NO: 1 or a fragment of a nucleic acid sequence having a sequence as set forth in SEQ ID NO: 1.

Stryer (BIOCHEMISTRY 3rd edition, New York, 1988, page 72) disclose of the building blocks of DNA and shows the structure of Adenine, Guanine, Thymine and Cytosine. Each of these molecules is a "fragment" of the isolated nucleic acid sequence as set forth in SEQ ID NO: 1.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

5. The rejection of claims 1, 4-9, 16, 18-20, 31 and 33 under 35 U.S.C. 102(e) as being anticipated by Lee *et al* is maintained. Additionally this rejection is applied to newly added claims 45-49.

Applicants are asserting that Lee et al do not disclose any sequence of the M antigen of H. capsulatum or its complement or any fragment thereof. Applicants further assert that Lee et al do not disclose a sequence "substantially the same as" SEQ ID NO: 1. Applicants conclude that anyone of skill in the art would understand that rRNA-encoding DNA is not substantially similar to M antigen encoding DNA.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants are asserting that Lee et al do not disclose any sequence of the M antigen of H. capsulatum or its complement or any fragment thereof. However, as set forth above, there is no length limit to the "fragment" nor is there an associated function that the fragment must display. Consequently, fragments as small as single amino acid encoding triplets or even single point nucleotides met the definition of a "fragment." Given that Lee et al disclose of overlapping sequences with greater than 1 nucleotide and greater than 1 amino acid encoding region, the disclosure of Lee et al is deemed to anticipate the claimed fragments.

Finally, Applicants further assert that Lee et al do not disclose a sequence "substantially the same as" SEQ ID NO: 1, and that clearly anyone of skill in the art would understand that rRNA-encoding DNA is not substantially similar to M antigen encoding DNA.. However, as set forth above, there is no true definition as to what the metes and bounds of "substantially the same" are. Clearly the definition of "substitution, deletion and/or addition of one or more nucleotides" (Specification page 19) has been met.

The claims are directed to an isolated nucleic acid specific to Histoplasma capsulatum comprising, a nucleic acid comprising SEQ ID NO: 1, substantially the same as SEQ ID NO: 1, and fragments of SEQ ID NO: 1, as well as vectors and host cells comprising the DNA sequences.

Lee *et al* (US Patent Number 5,693,501) disclose of isolated nucleic acids specific to Histoplasma capsulatum as well as their presence in vectors and host cells. (See claims and column 6).

In view that Lee *et al* disclose of isolated nucleic acids specific to Histoplasma capsulatum as well as vectors and host cells, the disclosure of Lee *et al* is deemed to be substantially the same as the claimed SEQ ID NO: 1. Furthermore, since the nucleic acid disclosed by Lee *et al* shares multiple nucleotides in common, the disclosure of Lee *et al* is also deemed to anticipate the claimed fragment language.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (571) 272-0861. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

February 5, 2004